

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 05-614
)	
ACAMBIS INC. and)	
ACAMBIS, PLC,)	
)	
Defendants.)	

DEFENDANTS' ANSWER

Defendants Acambis Inc. and Acambis, plc (collectively "Defendants" or "Acambis"), hereby answer and otherwise respond to the Complaint of Bavarian Nordic A/S ("Plaintiff" or "BN") as follows:

FIRST DEFENSE – FED. R. CIV. P. 8(b)

NATURE OF CASE

1. Defendants deny that they have committed any acts of unfair competition, conversion, or misappropriation of trade secrets in violation of the laws of the United States or the State of Delaware. Defendants further deny that BN is entitled to any relief on any of the claims set forth in the Complaint.

JURISDICTION

2. Defendants admit that this action is between parties whose citizenship is diverse and that BN seeks relief in excess of \$75,000. Defendants further admit that BN cites the Lanham Act as providing federal question subject matter jurisdiction under 28 U.S.C. § 1338. Defendants deny the remaining allegations set forth in Paragraph 2 of the Complaint insofar as they constitute legal conclusions to which no response is required.

3. Defendants admit that this Court has personal jurisdiction in this matter and that venue lies in this District. Defendants deny the remaining allegations set forth in Paragraph 3 of the Complaint insofar as they constitute legal conclusions to which no response is required.

THE PARTIES

4. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 4 of the Complaint and therefore deny those allegations. Defendants further deny that BN owns any proprietary information or material upon which a claim may be based against Acambis.

5. Defendants deny that the acts complained of in the Complaint occurred in Delaware. Defendants admit the remaining allegations set forth in Paragraph 5 of the Complaint.

6. Defendants deny that the acts complained of in the Complaint occurred in Delaware. Defendants admit the remaining allegations set forth in Paragraph 6 of the Complaint.

7. Defendants deny the allegations set forth in Paragraph 7 of the Complaint insofar as they constitute legal conclusions to which no response is required. Defendants admit that Acambis Inc. and Acambis plc share research personnel and jointly market vaccine product to the U.S. Government.

FACTUAL BACKGROUND

8. Defendants admit that the allegations set forth in Paragraph 8 of the Complaint are generally correct.

9. Defendants admit that the allegations set forth in Paragraph 9 of the Complaint are generally correct, and affirmatively aver that other smallpox vaccines – including some that are derived from the Dryvax® virus strain and some that are derived from other virus strains – are being currently evaluated.

10. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 10 of the Complaint and therefore deny those allegations.

11. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 11 of the Complaint and therefore deny those allegations.

12. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 12 of the Complaint and therefore deny those allegations.

13. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 13 of the Complaint and therefore deny those allegations.

14. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 14 of the Complaint and therefore deny those allegations. Defendants affirmatively aver that in an action filed contemporaneous with this suit before the U.S. International Trade Commission (“ITC action”), BN has accused Defendants of infringing the patents identified in Paragraph 14. In that forum, Defendants will challenge the alleged infringement, validity, and enforceability of the patents.

15. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 15 of the Complaint and therefore deny those allegations.

16. Defendants admit the allegations set forth in Paragraph 16 of the Complaint.

17. Defendants deny providing ACAM2000 vaccine under the contract awarded in September 2000. Defendants admit the remainder of the allegations set forth in Paragraph 17 of the Complaint. Defendants affirmatively aver that Acambis received a competitively awarded contract from the U.S. Government in September 2000 to research, develop and license a smallpox vaccine derived from the same vaccine strain as Dryvax® (ACAM1000), and that Acambis received a second competitively awarded U.S. Government contract in November 2001 to research, develop, manufacture and license a smallpox vaccine derived from the same vaccine strain as Dryvax® (ACAM2000).

18. Defendants deny the allegations set forth in Paragraph 18 of the Complaint.

19. Defendants admit that Baxter Healthcare SA (“Baxter”) is Acambis Inc.’s subcontract manufacturer of MVA3000 under two prime contracts between the U.S. Government and Acambis Inc. Defendant further admits that Baxter manufactures or intends to manufacture MVA3000 in Europe, at least in substantial part, for delivery in the United States to the U.S. Government. Defendant denies the remainder of the allegations in Paragraph 19 of the Complaint. Defendants also affirmatively aver that their only current MVA3000 “customer” in the United States is the U.S. Government.

20. Defendants deny the allegations set forth in Paragraph 20 of the Complaint. Defendants further deny the allegations set forth in Paragraph 20 of the Complaint insofar as they constitute legal conclusions to which no response is required.

21. Defendants deny the allegations set forth in Paragraph 21 of the Complaint. Defendants further deny the allegations set forth in Paragraph 21 of the Complaint insofar as they constitute legal conclusions to which no response is required.

22. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 22 of the Complaint and therefore deny those allegations.

23. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 23 of the Complaint and therefore deny those allegations. Defendants deny that BN holds an exclusive license for the commercialization of all Modified Vaccinia Ankara ("MVA") strains.

24. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 24 of the Complaint and therefore deny those allegations.

25. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 25 of the Complaint and therefore deny those allegations.

26. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 26 of the Complaint and therefore deny those allegations.

27. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 27 of the Complaint and therefore deny those allegations.

28. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 28 of the Complaint and therefore deny those allegations. Defendants deny that they were under any restriction with respect to the use of any MVA strain provided to them by the NIH.

29. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 29 of the Complaint and therefore deny those allegations.

30. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 30 of the Complaint and therefore deny those allegations.

31. Defendants admit that Acambis plc entered into an agreement entitled "Secrecy Agreement" with BN in February 2002, but deny the remaining allegations set forth in Paragraph 31.

32. Defendants admit that personnel from Acambis and BN met at Acambis' offices in Cambridge, Massachusetts, on June 12, 2002, and that Thomas Monath, the Chief Scientific Officer of Acambis Inc., attended some or all of the meeting. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 32 and therefore deny those allegations. Defendants further deny that BN disclosed any non-public, confidential or proprietary

information during that meeting, or that Defendants misappropriated any such information for their own commercial benefit.

33. Defendants admit that sometime in 2002, BN delivered a draft outline of a proposal for a potential collaboration between BN and Acambis. Defendants deny the remaining allegations set forth in Paragraph 33.

34. Defendants admit that the allegations set forth in Paragraph 34 of the Complaint are generally correct, but affirmatively aver that the U.S. Government expressed an interest in stockpiling smallpox vaccines prior to September 11, 2001, and acted on that interest by competitively awarding Acambis a smallpox vaccine contract in September 2000 (ACAM1000).

35. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 35 of the Complaint and therefore deny those allegations. Defendants admit that personnel from Acambis and BN met at Acambis' offices in Cambridge, Massachusetts, on June 12, 2002, but affirmatively aver that neither NIAID nor NIH were present at, nor participated in, that meeting.

36. Defendants admit that NIAID NIH released the First RFP in September 2002 outlining the requirements for an attenuated form of the smallpox vaccine virus, including dosage. Defendants deny the remaining allegations in Paragraph 36 of the Complaint. Defendants affirmatively aver that the First RFP invited any offeror to enter into "collaborative opportunities" with the NIH and that such opportunities were specifically not part of the RFP. These "opportunities" included "the availability of master seed stock of MVA from NIAID."

37. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 37 of the Complaint and therefore deny those allegations.

38. Defendants admit the allegations set forth in Paragraph 38 of the Complaint.

39. Defendants admit receiving MVA Virus 572.FHE-22.02.1974, which was plaque purified by Dr. Bernard Moss, from NIH NIAID. Defendants deny the remainder of the allegations in Paragraph 39. Defendants affirmatively aver being in possession of MVA vaccine strains prior to the contract award in February 2003.

40. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 40 of the Complaint and therefore deny those allegations.

41. Defendants admit that they initiated human clinical trials of MVA3000 under a U.S. Investigational New Drug (IND) application in 2004 and announced results of those trials in April 2005. Defendants deny the remaining allegations set forth in Paragraph 41 of the Complaint.

42. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 42 of the Complaint and therefore deny those allegations. Defendants deny that BN disclosed any non-public, confidential or proprietary information to Defendants, or that Defendants misappropriated any such information for their own commercial benefit.

43. Defendants deny the allegations set forth in Paragraph 43 of the Complaint.

COUNT I – TORTIOUS CONVERSION

44. Defendants incorporate Paragraphs 1 through 43 above by reference.
45. Defendants deny the allegations set forth in Paragraph 45 of the Complaint.
46. Defendants deny the allegations set forth in Paragraph 46 of the Complaint.
47. Defendants deny the allegations set forth in Paragraph 47 of the Complaint.
48. Defendants deny the allegations set forth in Paragraph 48 of the Complaint.
49. Defendants deny the allegations set forth in Paragraph 49 of the Complaint.
50. Defendants deny the allegations set forth in Paragraph 50 of the Complaint.

COUNT II – MISAPPROPRIATION OF TRADE SECRETS

51. Defendants incorporate Paragraphs 1 through 50 above by reference.
52. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 52 of the Complaint and therefore deny those allegations. Defendants deny that BN disclosed any non-public, confidential or proprietary information to Defendants, or that Defendants misappropriated any such information for their own commercial benefit.
53. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 53 of the Complaint and therefore deny

those allegations. Defendants deny that BN disclosed any non-public, confidential or proprietary information to Defendants, or that Defendants misappropriated any such information for their own commercial benefit.

54. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 54 of the Complaint and therefore deny those allegations. Defendants deny that BN disclosed any non-public, confidential or proprietary information to Defendants, or that Defendants misappropriated any such information for their own commercial benefit.

55. Defendants deny the allegations set forth in Paragraph 55 of the Complaint.

56. Defendants admit that, as of June 12, 2002, they were aware that BN was seeking to develop a MVA-based smallpox vaccine. Defendants deny the remaining allegations set forth in Paragraph 56 of the Complaint.

57. Defendants deny the allegations set forth in Paragraph 57 of the Complaint.

58. Defendants deny the allegations set forth in Paragraph 58 of the Complaint.

59. Defendants deny the allegations set forth in Paragraph 59 of the Complaint.

60. Defendants deny the allegations set forth in Paragraph 60 of the Complaint.

61. Defendants deny the allegations set forth in Paragraph 61 of the Complaint.

COUNT III – UNFAIR TRADE PRACTICES

62. Defendants incorporate Paragraphs 1 through 61 above by reference.

63. Defendants deny the allegations set forth in Paragraph 63 of the Complaint.

64. Defendants deny the allegations set forth in Paragraph 64 of the Complaint.

65. Defendants deny the allegations set forth in Paragraph 65 of the Complaint.

66. Defendants deny the allegations set forth in Paragraph 66 of the Complaint.

COUNT IV – LANHAM ACT UNFAIR COMPETITION

67. Defendants incorporate Paragraphs 1 through 66 above by reference.

68. Defendants deny the allegations set forth in Paragraph 68 of the Complaint.

69. Defendants deny the allegations set forth in Paragraph 69 of the Complaint.

PRAYER FOR RELIEF

Defendants deny that BN is entitled to any relief in this matter.

SECOND DEFENSE – FED. R. CIV. P. 8(c)

a. BN brings this action with unclean hands by using the processes of this Court for improper business purposes.

b. BN's claims are barred by the doctrine of laches, estoppel, and/or waiver insofar as BN was aware of the alleged basis for the claims made in the Complaint at

least as early as February 2003 – prior to the U.S. Government’s subsequent MVA-related RFPs – but took no action. Such delay has caused and/or will cause prejudice and injury to Defendants and third parties.

- c. Some or all of BN’s claims may be subject to binding arbitration.
- d. BN’s claims are barred insofar as BN and/or its agents provided the property and/or information at issue to the U.S. Government without restriction.
- e. BN’s claims are barred insofar as BN and/or its agents did not have the authority to restrict the U.S. Government’s use and provision of the property and/or information at issue.
- f. BN’s claims are subject to the doctrine of inequitable conduct before the U.S. Patent and Trademark Office insofar as the claims are based on BN’s alleged patent rights.

THIRD DEFENSE – FED. R. CIV. P. 12(b)(6)

BN fails to state any claim upon which relief can be granted under any theory.

FOURTH DEFENSE – FED. R. CIV. P. 12(b)(7)

BN’s claims must be dismissed for failure to join the U.S. Government as an indispensable party insofar as the U.S. Government owns or will own the vaccines sought by BN’s request for injunctive relief. That request includes a demand for the “return of all MVA virus and its progeny in the possession of [Defendants] and/or [their] suppliers.” Prayer for Relief at ¶ D. The U.S. Government is also an indispensable party insofar as it is alleged in the Complaint (*see, e.g.*, ¶ 39) to be Defendants’ supplier of the MVA strain used to develop and manufacture Defendants’ MVA3000 vaccine. The proper forum for

pursuing relief against the U.S. Government is the U.S. Court of Federal Claims pursuant to 19 U.S.C. § 1337(l) and/or the Tucker Act, 28 U.S.C. § 1491 *et seq.*

FIFTH DEFENSE – FED. R. CIV. P. 12(e)

BN's claim for trade secret violations under Delaware law fails for lack of specificity.

SIXTH DEFENSE

Pursuant to 28 U.S.C. § 1659, this action must be stayed pending a final determination of BN's ITC action as BN's claims in this case involve the same issues involved in the ITC action, which alleges patent infringement and trade secret violations. In fact, all of the allegations set forth in the "Factual Background" of the Complaint in this case are taken almost *verbatim* from the factual allegations set forth in BN's ITC complaint.

SEVENTH DEFENSE

Defendants reserve the right to present additional affirmative defenses and/or responses and/or counterclaims as such matters are revealed during the course of the litigation.

DEMAND FOR A JURY TRIAL

Defendants respectfully demand a trial by jury on all issues, claims, and causes of action appropriately tried to a jury.

MORRIS, NICHOLS, ARSHT & TUNNELL

/s/ Mary B. Graham

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September 8, 2005

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CERTIFICATE OF SERVICE

I hereby certify that on September 8, 2005, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

John W. Shaw
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Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on September 8, 2005, upon the following individuals in the manner indicated:

BY HAND:

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